K110726

DEC 2 3 2011

510(k) Summary: Roche cobas 8000 Modular Analyzer Series (Revised 12-20-2011)

Introduction

The information in this 510(k) Summary is being submitted in accordance with the requirements of 21 CFR 807.92.

Submitter name, address, contact

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Date prepared: December 20, 2011

Device Name

Proprietary name: Roche Acetaminophen assay

Common names: Enzymatic assay for the determination of acetaminophen

Classification names: Acetaminophen test system (21 CFR 862.3030). Product code LDP

Predicate Device

We claim substantial equivalence to the following predicate devices: Roche COBAS Integra Acetaminophen assay (K991598), the Roche/Hitachi Acetaminophen assay (K013757) and the cobas c501 Acetaminophen assay (K060373).

Intended use / Indications for use

The Roche Acetaminophen assay is an in vitro test for the quantitative determination of toxic levels of acetaminophen in serum and plasma on Roche COBAS Integra, Roche/ Hitachi and cobas c system analyzers.

Device Description

The Roche Diagnostics Acetaminophen assays under consideration in this submission are the same assays as were cleared on the COBAS Integra in K991598, Hitachi 917 in K013757 and cobas c501 in K060373 for the quantitative determination of toxic levels of Acetaminophen in human serum and plasma on automated clinical chemistry analyzers. The same reagents are used on all three systems.
Acetaminophen is hydrolyzed by an arylacylamidase to yield p-aminophenol

and acetate. Subsequently, the p-aminophenol is converted to an indophenol in the presence of o-cresol and a periodate catalyst. The production of indophenol is followed colorimetrically. The change in absorbance is directly proportional to the quantitative drug concentration in the sample.

The following tables illustrate the similarities and differences between the current Acetaminophen assays and the predicate assays

Table A- cobas c501

Feature	Cobas c501 Acetaminophen	Cobas c501 Acetaminophen (Predicate K060373)
Indications for Use	In Vitro test for the quantitative determination of toxic levels of acetaminophen in serum and plasma on Roche/ Hitachi and cobas c systems	Same
Technology	Enzymatic- end point	Same
Sample types	Serum and plasma	Same
Calibrators	COBAS Integra calibrators	Same
Reagents	R1: Sodium periodote 3.75 mmol/L R2: Arlyacylamidase (microbial)≥7000U/L;; o-cresol 3.75 mmol/L	Same
Analytical Sensitivity	LoB 1.2 µg/ml LoD 2.4 µg/ml LoQ 15 µg/ml	Lower detection level (LDL) 1.2 µg/ml
Measuring range	15-500 µg/ml	1.2-500 µg/ml
Interferences	Bilirubin interference at Acetaminophen level of 15, 30 and 50 µg/ml	Bilirubin interference at Acetaminophen level of 50µg/ml

Table B- Hitachi 917

Feature	Hitachi 917 Acetaminophen	Hitachi 917 Acetaminophen (Predicate K060373)
Indications for Use	The Roche Acetaminophen assay is for the quantitative determination of toxic levels of acetaminophen in human serum or plasma on automated clinical chemistry analyzers	Same
Technology	Enzymatic- end point	Same
Sample types	Serum and plasma	Same
Calibrators	COBAS Integra calibrators	Same
Reagents	R1: Sodium periodote 3.75 mmol/L R2: Arlyacylamidase (microbial)≥7000U/L;; o-cresol 3.75 mmol/L	Same
Analytical Sensitivity	LoB 1.2 µg/ml LoD 2.4 µg/ml LoQ 15 µg/ml	Lower detection level (LDL) 1.2 µg/ml
Measuring range	15-500 µg/ml	1.2-600 µg/ml
Interferences	Bilirubin interference at Acetaminophen level of 15, 30 and 50 µg/ml.	Bilirubin interference at Acetaminophen level of 50µg/ml

Table C – COBAS Integra 800

Feature	COBAS Integra Acetaminophen	COBAS Integra Acetaminophen (Predicate K991598)
Indications for Use	In Vitro test for the quantitative determination of toxic levels of acetaminophen in serum or heparinized plasma on COBAS INTEGRA systems	Same
Technology	Enzymatic- end point	Same
Sample types	Serum and plasma	Same
Calibrators	COBAS Integra calibrators	Same
Reagents	R1: Arlyacylamidase (microbial)≥7000U/L;; o-cresol 3.75 mmol/L R2: Sodium periodote 3.75 mmol/L	Same
Analytical Sensitivity	LoB 1.2 µg/ml LoD 2.4 µg/ml LoQ 15.0 µg/ml	Lower detection level (LDL) 0.7 µg/ml
Measuring range	15-300 µg/ml	0.7-300 µg/ml
Interferences	Bilirubin interference at Acetaminophen level of 15, 30 and 50 µg/ml.	Bilirubin interference at Acetaminophen level of 50µg/ml

Conclusion The Acetaminophen assays are substantially equivalence to the following predicate devices: Roche COBAS Integra Acetaminophen assay (K991598), the Roche/Hitachi Acetaminophen assay (K013757) and the cobas c501 Acetaminophen assay (K060373). This submission included additional information on interference caused by bilirubin in order to help improve the safe and effective use of the products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Roche Diagnostics
c/o Angelo Pereira
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Indianapolis, IN 46250-0416

DEC 23 2011

Re: k110726
Trade Name: ROCHE ACETAMINOPHEN ASSAY
Regulation Number: 21 CFR §862.3030
Regulation Name: Acetaminophen Test System
Regulatory Class: Class II
Product Codes: LDP
Dated: December 7, 2011
Received: December 8, 2011

Dear Mr. Pereira:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Roche Acetaminophen Assay

Indications For Use:

The Roche Acetaminophen assay is an in vitro test for the quantitative determination of toxic levels of acetaminophen in serum and plasma on Roche COBAS Integra, Roche/ Hitachi and cobas c system analyzers.

Prescription Use XXX AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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